APPENDIX A

Proposed Count 1:

(RE 294 Claim 1) A medicinal aerosol formulation, which consists essentially of:

(a) a therapeutically effective amount of a particulate medicament;

(b) a propellant; and

(c) a stabilizer selected from an amino acid, a derivative thereof, or a mixture of the foregoing

whereby said medicament and said stabilizer are different.

OR

(Applicants' Claim 36) A medicinal aerosol formulation, which consists essentially of:

(a) a therapeutically effective amount of a particulate medicament;

(b) a propellant; and

(c) a suspension-enhancing amino acid,

whereby said medicament and said suspension-enhancing amino acid are different.

OR

(Applicants' Claim 50) A medicinal aerosol formulation which consists essentially of

(a) a therapeutically effective amount of a particulate medicament;

(b) a propellant; and

(c) a suspension-enhancing amino acid, in addition to the medicament.

OR

(Applicants' Claim 51) A medicinal aerosol formulation, which consists essentially of:

(a) a therapeutically effective amount of a particulate medicament;

(b) a propellant; and

(c) an amino acid;

whereby said medicament of (a) and said amino acid of (c) are different.

OR

(Applicants' Claim 65) A medicinal aerosol formulation which consists essentially of

(a) a therapeutically effective amount of a particulate medicament;

(b) a propellant; and

(c) an amino acid in addition to the medicament.

Proposed Count 2:

(RE 294 Claim 14) A metered dose inhaler containing a medicinal aerosol formulation, the formulation consisting essentially of:

(a) a drug in particulate form in a therapeutically effective amount;

(b) a propellant; and

(c) a suitable stabilizer selected from an amino acid, an amino acid derivative, or a mixture of the foregoing, present in an amount sufficient to stabilize the formulation to prevent settling, creaming or flocculation for a time sufficient to allow reproducible dosing of the drug after agitation of the formulation

whereby said medicament and said stabilizer are different.

OR

(Applicants' Claim 46) A metered dose inhaler containing a medicinal aerosol formulation, the formulation consisting essentially of:

(a) a drug in particulate form in a therapeutically effective amount;

(b) a propellant; and

(c) a suitable suspension-enhancing amino acid, present in an amount sufficient to prevent settling, creaming, or flocculation of the formulation for a time sufficient to allow reproducible dosing of the drug after agitation of the formulation,

whereby said medicament and said suspension-enhancing amino acid are different.

OR

(Applicants' Claim 61) A metered dose inhaler containing a medicinal aerosol formulation, the formulation consisting essentially of:

(a) a drug in particulate form in a therapeutically effective amount;

(b) a propellant; and

(c) an amino-acid present in an amount sufficient to prevent settling, creaming, or flocculation of the formulation for a time sufficient to allow reproducible dosing of the drug after agitation of the formulation,

whereby said medicament of (a) and said amino acid of (c) are different.

Proposed Count 3:

(RE 294 Claim 9) A method of preparing a medicinal aerosol formulation according to claim 1, which comprises:

(a) combining

(i) said medicament in an amount sufficient to provide a plurality of therapeutically effective doses,

(ii) said propellant in an amount sufficient to propel a plurality of said therapeutically effective doses from an aerosol canister; and

(iii) said stabilizer in an amount effective to stabilize the formulation; and

(b) dispersing components (i), (ii) and (iii).

OR

(RE 294 Claim 13) A method for stabilizing a suspension aerosol formulation comprising a propellant and a particulate drug which comprises,

incorporating into the formulation a stabilizer selected from the group consisting of a suitable amino acid, a derivative thereof, or any mixture of the foregoing, in an amount which is effective to prevent settling, creaming, or flocculation of the formulation for a time sufficient to allow reproducible dosing of the drug after agitation of the formulation

whereby said medicament and said stabilizer are different.

OR

(Applicants' Claim 41) A method of preparing a medicinal aerosol formulation according to claim 36 which comprises:

(a) combining

(i) said medicament in an amount sufficient to provide a plurality of therapeutically effective doses;

(ii) said propellant in an amount sufficient to propel a plurality of said therapeutically effective doses from an aerosol canister; and

(iii) said suspension-enhancing amino acid in an amount effective to enhance the suspension quality of the formulation; and

(b) dispersing components (i), (ii), and (iii).

OR

(Applicants' Claim 45) A method comprising incorporating into a formulation that consists essentially of a propellant and a particulate drug a suspension-enhancing amino acid, in an amount which is effective to prevent settling, creaming, or flocculation of the formulation for a time sufficient to allow reproducible dosing of the drug after agitation of the formulation, whereby said drug and said amino acid are different.

OR

(Applicants' Claim 56) A method of preparing a medicinal aerosol formulation according to claim 51, which comprises:

(a) combining

(i) said medicament in an amount sufficient to provide a plurality of therapeutically effective doses;

(ii) said propellant in an amount sufficient to propel a plurality of said therapeutically effective doses from an aerosol canister; and

(iii) said amino acid in an amount effective to enhance the stability of the formulation; and

(b) dispersing components (i), (ii), and (iii).

OR

(Applicants' Claim 60) A method comprising incorporating into a formulation that consists essentially of a propellant and a particulate drug a suitable amino acid in an amount which is effective to prevent settling, creaming, or flocculation of the formulation for a time sufficient to allow reproducible dosing of the drug after agitation of the formulation, whereby said drug and said amino acid are different.

Proposed Count 4

(RE 294 Claim 11) A method of treating in an animal a condition capable of treatment by oral or nasal inhalation, which comprises, administering a formulation according to claim 1 to said animal by oral or nasal inhalation.

OR

(Applicants' Claim 42) A method of treating in an animal a condition capable of treatment by oral or nasal inhalation, which comprises, administering a formulation according to claim 36 to said animal by oral or nasal inhalation.

OR

(Applicants' Claim 57) A method of treating in an animal a condition capable of treatment by oral or nasal inhalation, which comprises, administering a formulation according to claim 51 to said animal by oral or nasal inhalation.